DARCO

K061808

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Huntington, WV 25701

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510(k) Summary

AUG 17 2006

Submitter Data: Darco International, Inc.
810 Memorial Blvd.
Huntington WV 25701
Phone- (304) 522-4883
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Contact: Mark S. Cooper

Date: June 26, 2006

Device Name: DARCO Locking Bone Plate System

Common Name: Bone Fixation Plate

Classification Name: Single/Multiple component metallic bone fixation appliance (per 21 CFR 888.3030)

Legally Marketed Predicate Device: Normed Titanium Osteotomy Plating System (K022325)

Device Description: The DARCO Locking Bone Plate System is designed with rhombus (parallelogram) plates of biocompatible titanium. The plates use either 2.7mm or 3.5mm screws which intersect each other in pairs. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary essentially through different curvatures, material strengths, lengths, number of plate holes and through different grades or bridge widths.

Intended Use: The DARCO Locking Bone Plate system is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes. The system can be used in both adult and pediatric patients.

Technological Characteristics: There are no differences in the technological characteristics of the DARCO Locking Bone Plate System and the predicate device.

Performance Data: No clinical or non-clinical tests were used in the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2006

DARCO International
% Mr. Mark S. Cooper
Director of Regulatory Affairs
810 Memorial Boulevard
Huntington, West Virginia 25701

Re: K061808
Trade/Device Name: DARCO Locking Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: June 26, 2006
Received: June 28, 2006

Dear Mr. Cooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Mechum for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)
Statement of Indications for Use

510(k) number (if known)	K061808
Device Name	DARCO Locking Bone Plate System
Indications for Use	The DARCO Locking Bone Plate System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system may be used in both adult and pediatric patients.

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over the Counter Use_____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Barbara Bruchmann
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061808